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M.G.)  
4/24/03U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

## INFORMATION DISCLOSURE STATEMENT

Docket Number:  
11701/53301Application Number  
**09/299,562**Filing Date  
**April 27, 1999**Examiner  
**Sandra WEGERT**Art Unit  
**1647**

Invention Title

**PHARMACEUTICAL COMPOSITIONS  
CONTAINING PLASMA PROTEIN**Inventors  
**HEGEDUS et al.**Address to:  
Commissioner for Patents  
Washington D.C. 20231

*I hereby certify that this correspondence is being deposited with the  
United States Postal Service with sufficient postage as first class mail  
in an envelope addressed to: Commissioner for Patents,  
Washington, D.C. 20231 on:*

Date: 4/7/03Signature: Sandra Wegert

Sir:

1. In accordance with the duty of disclosure under 37 C.F.R. § 1.56 and in conformance with the procedures of 35 U.S.C. §§ 1.97 and 1.98 and M.P.E.P. § 609, attorneys for Applicants hereby bring the following references to the attention of the Examiner. These references are listed on the attached modified PTO Form No. 1449. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom. The filing of this Information Disclosure Statement and the enclosed PTO Form No. 1449 shall not be construed as an admission that the information cited is prior art, or is considered to be material to patentability as defined in 37 C.F.R. § 1.56(b).
2. A copy of each patent, publication or other information listed on the modified PTO form 1449 is enclosed.
3. A concise explanation of the relevance of the following non-English language reference is found in the specification:  

DE 37 02 105 A1  
HU 198 381
4. The Commissioner is hereby authorized to charge payment of the 37 C.F.R. §1.17(p) (submission of an information disclosure statement under §1.97(c)) fee of **\$180.00** and any additional fees that may be required to the deposit account of **Kenyon & Kenyon**, deposit account number **11-0600**. A copy of this communication is enclosed for charging purposes.

Dated: 4/7/03By: John K. Lo

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT PTO-1449	ATTY. DOCKET NO. 11701/53301	APR 11 2003 SERIAL NO 2003 09/299,562 TECH CENTER 1600/2900
	APPLICANT HEGEDUS et al.	
	FILING DATE April 27, 1999	GROUP 1647

## U. S. PATENT DOCUMENTS

EXAMINER INITIAL	PATENT NUMBER	PATENT DATE	NAME	CLAS S	SUBCLAS S	FILING DATE*
	5,560,933	October 1, 1996	Soon-Shiong et al.			
	5,621,001	April 15, 1997	Canetta et al.			
	5,665,761	September 9, 1997	Canetta et al.			
	5,670,537	September 23, 1997	Canetta et al.			

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
						*	0
	37 02 105 A1	August 4, 1988	Germany				
	198381	January 24, 1987	Hungary				

## OTHER DOCUMENTS

EXAMINER INITIAL		AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.
		"GUIDANCE FOR INDUSTRY, Extended Release Oral Dosage Forms: Development, Evaluation, and Application of In Vitro/In Vivo Correlations", U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER) (September 1997), 1-24.
		Aarset et al., "A nurse with a rash on her neck", Ansquer et al., "Survival in early-onset BRCA1 breast-cancer patients", Shimomura et al., "Effects of Taxol on blood cells", Ashok et al., "Termination of pregnancy at 9-13 weeks' amenorrhoea with mifepristone and misoprostol", The Lancet (Agust 15, 1998), 352(9127):540-542.
		Bejinen et al., "Bioanalysis, Pharmacokinetics, and Pharmacodynamics of the Novel Anticancer Drug Paclitaxel (Taxol)", Seminars in Oncology (October 1994), 21(5):53-62.
		Eiseman et al., "Plasma pharmacokinetics and tissue distribution of paclitaxel in DC <sub>2</sub> F <sub>1</sub> mice", Cancer Chemotherapy and Pharmacology (1994), 34: 465-471.
		Guitton et al., "Quantitation of propofol in whole blood by gas chromatography-mass spectrometry", Journal of Chromatography B: Biomedical Applications (July 21, 1995), 669:358-365.

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EXAMINER INITIAL	AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.
	Hallbach et al., "Determination of Lamotrigine, Carbamazepine and Carbamazepine Epoxide in Human Serum by Gas Chromatography Mass Spectrometry", <i>European Journal of Clinical Chemistry and Clinical Biochemistry</i> (October 1997), 35(10):755-759.
	Johansen et al., "Automated analysis of free and total concentrations of three antiepileptic drugs in plasma with on-line dialysis and high-performance liquid chromatography", <i>Journal of Chromatography B: Biomedical Applications</i> (July 21, 1995) 669: 281-288.
	Olah et al., "Molecular Mechanisms in the Antiproliferative Action of Taxol and Tiazofurin", <i>Anticancer Research - International Journal of Cancer Research and Treatment</i> (Sept.-Oct. 1996), 16:2469-2477.
	Pavan et al., "Monitoring Propofol Serum Levels by Rapid and Sensitive Reversed-Phase High-Performance Liquid Chromatography During Prolonged Sedation in ICU Patients", <i>Chromatographic Science</i> (May 1992), 30(5):164-166.
	Puls et al., "MicroTICAS - The Design of an Inexpensive Video-Based Microphotometer / Computer System for DNA Ploidy Studies", <i>Analytical and Quantitative Cytology Histology</i> (1986), 8(1):1-7.
	Rivory et al., "Identification and Properties of a Major Plasma Metabolite of Irinotecan (CPT-11) Isolated from the Plasma of Patients", <i>Cancer Research</i> (August 15, 1996), 56:3689-3694.
	Rowinsky et al., "Taxol: A Novel Investigational Antimicrotubule Agent", <i>Journal of the National Cancer Institute</i> (August 1990), 82(15):1247-1259.
	Royer et al., "Paclitaxel Metabolites in Human Plasma and Urine: Identification of 6 $\alpha$ -Hydroxytaxol, 7-Epitaxol and Taxol Hydrolysis Products Using Liquid Chromatography/Atmospheric-pressure Chemical Ionization Mass Spectrometry", <i>Rapid Communications in Mass Spectrometry</i> (1995), 9:495-502.
	Schäfer-Korting et al., "Influence of Serum Protein Binding on the <i>In Vitro</i> Activity of Antifungal Agents", <i>Infection</i> (1995), 23(5):292-297.
	Sottani et al., "Structural Characterization of Mono-and Dihydroxylated Metabolites of Paclitaxel in Rat Bile Using Liquid Chromatography / Ion Spray Tandem Mass Spectrometry", <i>Rapid Communications in Mass Spectrometry</i> (1997), 11:1025-1032.
	Thomas et al., "15-Deoxyspergualin: A Novel Immunosuppressive Drug with Clinical Potential", <i>Annals of the New York Academy of Sciences</i> (1993) 685:175-192.

EXAMINER	DATE CONSIDERED
EXAMINER: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	